

FILING DATE

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FIRST NAMED APPLICANT ATTORNEY DOCKET NO 09/046.833 03/24/98 LIU HM11/0605 RONALD C FEDUS ARTUNIT, D PAPER NUMBER ENZO THERAPEUTICS INC ENZO BIOCHEM INC 527 MADISON AVENUE 9TH FLOOR DATE MAILED: NEW YORK NY 10022 06/05/98 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS **OFFICE ACTION SUMMARY** Responsive to communication(s) filed on ☐ This action is FINAL. ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213. A shortened statutory period for response to this action is set to expire ______(3) _____m::th(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR **Disposition of Claims** (£) _ 68 ___ is/zzz pending in the application. is/are withdrawn from consideration. ☐ Claim(s) is/are allowed. 1 Claim(s) 68 is/ess rejected. ☐ Claim(s) is/are objected to. ☐ Claims are subject to restriction or election requirement. Application Papers See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. (Substitution is/are objected to by the Examiner. The drawing(s) filed on _ ☐ The proposed drawing correction, filed on _ _ is 🗌 approved 🔲 disapproved. ☐ The specification is objected to by the Examiner. ☐ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)). *Certified copies not received: Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) Notice of Reference Cited, PTO-892 ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _ ☐ Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Applicants however, need not submit a new computer readable form of the Sequence Listing if the sequences present in the instant case are the same as those in the parent case. However, the specification must contain a paper copy of the Sequence Listing and applicants must request in writing that the CRF in the parent case be used to prepare a file for the offspring. In addition, applicants must submit a statement that the paper copy of the Sequence Listing in the offspring is identical to the computer readable form submitted in the parent case. Any response to this Office Action which does not include a complete response to this Sequence Listing requirement will be considered non-responsive.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claim 68 is rejected under 35 U.S.C. 102(b) as being anticipated by Salmons et al. or Smith.

Applicants claim a packaging cell line for propagating a viral vector independent of a helper virus, said vector comprising a nucleic acid component (stably integrated into the cell genome)

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and a non-nucleic acid component introduced into the cell by transient expression, stably integrated expression, etc.

Salmons et al. (Human Gene Therapy, Vol. 4, 1993, pp. 129-141, see whole article, particularly pp. 133-135) and Smith (Annu. Rev. Microbiol., Vol. 49, 1995, pp. 807-838, see whole article, particularly pp. 821-823) both recite packaging cell lines for propagating a viral vector independent of a helper virus wherein said viral vector is stably integrated into the genome of the host cell, wherein the viral vector is composed of nucleic acid and non-nucleic acid (i.e. protein) components and wherein the non-nucleic acid portion are introduced into the cell by stably integrated expression or transient expression. Therefore, Salmons et al. and Smith both teach the claimed invention.

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claim 68 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 is vague in that it recites improper Markush language. The members of a Markush group are linked by "and" not "or".

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No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-19065. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo June 4, 1998

DAVID GUZO
PRIMARY EXAMINER